



July 31, 2001

Kimberly Topper
Food and Drug Administration, CDER
Advisors and Consultant Staff, HFD-21
5600 Fishers Lane
Rockville, Maryland 20857

RE: Anesthetic and Life Support Drugs Advisory Committee
Non-malignant Pain management

Dear Ms. Topper:

This letter is written in comment to the use of opiate analgesics in patients with chronic pain of non-malignant etiology. For centuries patients with multiple chronic conditions have suffered the ravages of pain and the consequences of inadequate management of their pain. Their lives have been terribly affected, not only because of the effects of arthritis and other physical manifestations of pain but also because of the suffering associated with the process of non-malignant pain. While great strides have been made in our understanding of the pathophysiology of chronic non-malignant pain, we continue to have few options for therapy other than the use of narcotic analgesics. Patients with chronic non-malignant pain have, as a result, historically been under-treated by their physicians because of the physicians concerns of opiate abuse and narcotic addiction. Additionally, most patients tend to under treat themselves because of similar concerns. Their lot has been to be either ignored by the health care profession or instructed to "buck-up" and simply to live with their pain.

The use of narcotic analgesics to treat patients with cancer pain has been readily accepted and patients at the end of life are given adequate pain medication. This approach is certainly laudable and correct. However, I question the vision of the avoidance of pain management in patients that are still capable, with the relief of their pain, to continue to offer substantial benefits to their families as well as to society. While issues of addiction, diversion and abuse potential need to be addressed, there is no reason for the bulk of these patients to be denied these beneficial medications. The physician's ethical obligation in chronic non-malignant pain is similar to the obligation in managing cancer pain, i.e. to relieve the patient's suffering.

Recent advances have been made not only in our understanding of the management of patients with chronic non-malignant pain but also in identifying and avoiding the pit-falls of drug diversion and addiction. However, it is impossible to prevent all abuse that may potentially arise out of the existence of these medications. Better education of physicians, their staff and patients will help to result in less diversion and addiction problems. I can tell you that most physicians and their staffs are very aware of this problem, as are patients themselves, but methods for avoiding diversion are not well enough established or understood to prevent all episodes of abuse. Many drugs have the potential for diversion and abuse but are still part of the main stream of medical management. It defies logic to deny narcotic analgesic medications to patients in need because of the actions of a few individuals.

When the risk-benefit ratio of the use of opiate therapy in patients with non-malignant pain is looked at, the ratio is well within the beneficial range. Appropriate controls need to be devised, but denial of the use of these medications for patients by their physicians should not be an issue. Relief of our patient's suffering is at the core of our professional commitment.

I urge the advisory committee to allow the continued medical use of opiate analgesics in patients with chronic non-malignant pain and to devise appropriate guidelines for their usage. Only in this manner will we be able to free this patient population of the shackles that have held them for so many years.

Sincerely,

A handwritten signature in black ink, appearing to read "H. Kenney MD". The signature is fluid and cursive, with the initials "H.M." visible at the end.

Howard M. Kenney, MD